# DDMAC Research Team Report

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Marketing Pharmaceuticals in a Time of Change
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# Outline of Presentation

- Meet the research team
- Research in progress update
- Preliminary results from Brief Summary Study 1

# DTC Review Group Structure

**Direct-To-Consumer Review Group I**

Group leader: Bob Dean

*Metabolic/Endocrine, Analgesics/ Anesthetics,Rheumatology*
Kendra Jones,
Michael Sauers

*Dermatology/Dental, GI, Pulmonary/Allergy*
Shefali Doshi,
Robyn Tyler

*Oncology Drugs, Oncology Biologics*
Beverly Bowers
Stephanie Victor

Research Team

**Direct-To-Consumer Review Group II**

Group leader: Marci Kiester

*Cardio-renal*
Zarna Patel

*Psychiatry*
Susannah Hubert

*Neurology, Anti-Infectives, Opthalmology, Special Pathogens, Transplant*
Sharon Watson,
Twyla Thompson

*Anti-virals*
Aline Moukhtara

*Reproductive, Urology, Medical Imaging, Hematology*
Cynthia Collins
Carrie Newcomer

Kathryn Aikin

Amie O'Donoghue

Helen Sullivan

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# Research in Progress

- Research in Progress
  - Visual Distraction During Risk in DTC Television Ads
  - Presentation of Efficacy Information in DTC Print Ads
  - Toll-Free Number for Reporting Side Effects in DTC Television Ads
  - Impact of Incentives in DTC Print Ads
  - Presentation of Quantitative Information in DTC Print and Television Ads

# Visual Distraction Study

Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in DTC Prescription Drug Broadcast Advertisements

DDMAC Research Team, in conjunction with Nancy Ostrove (FDA, Office of the Commissioner), Scott Douglas (HHS, Office of the Assistant Secretary for Planning and Evaluation) and Jack Swasy (Kogod School of Business, American University)

# Visual Distraction Study Purpose

- Gather empirical evidence to address concerns that the use of competing, compelling visual information interferes with viewers' processing and comprehension of risk information
- Examine the role of textual elements in the processing of risk information
- Provide FDA with information on defining the presentation of the major statement as "clear, conspicuous, and neutral" as required by FDAAA

# Visual Distraction Study Status

- 30-day public comment period closed 1/30/09. Under OMB review now

# Efficacy Study

Consumer Understanding of Clinical Efficacy from the Display Pages of DTC Print Ads

# Efficacy Study Purpose

What information do consumers glean from print ads and how does this information correspond to physicians' assessments of the same drugs from the label?

# Efficacy Study Overview

- Phase I
  - Mental Models Research and Focus Groups with physicians
- Phase II
  - Internet survey of physicians
- Phase III
  - Internet experiment with consumers

# Efficacy Study Status

- Phase I underway
  - Expert model workshop completed November 2007.
  - Physician focus groups completed December 2008.
  - 60-day public comment period for mental models phase closed 1/24/09. Evaluating comments and preparing 30-day federal register notice and OMB submission.
- End of Phase III not expected until after 2010

# Toll-Free Study

Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs

# Toll-Free Study Purpose

Mandated by FDAAA

- Title IX of FDAAA amends section 502(n) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 352), by requiring printed direct-to-consumer (DTC) advertisements for prescription drug products to include the following statement printed in conspicuous text: 'You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/medwatch, or call 1-800-FDA-1088." Title IX of FDAAA also requires the Secretary of Health and Human Services (Secretary), in consultation with the Advisory Committee on Risk Communication, to conduct a study not later than six months after the date of enactment of FDAAA to determine if this statement is appropriate for inclusion in DTC television advertisements for prescription drug products. As part of this study, the Secretary shall consider whether the information in the statement described above would detract from the presentation of risk information in a DTC television advertisement.

# Toll-Free Study Status

- Presented preliminary design to Risk Communication Advisory Committee May 2008.
- 60-day public comment period closed 1/26/09. Evaluating comments and preparing 30-day federal register notice, OMB submission and RIHSC submission.

# Impact of Incentives in Direct-to-Consumer Print Advertising

Experimental Study of the Impact of Coupons Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits

# Impact of Incentives in DTC Ads Study Purpose

- Examine what impact, if any, the presence of a coupon may have on consumers' perceptions of product risks and benefits

# Impact of Incentives in DTC Ads Study Status

- 60-day public comment period closed 2/16/09. Evaluating comments and preparing 30-day federal register notice, OMB submission and RIHSC submission.

# Quantitative Information in DTC Print and Broadcast Ads Study

Presentation of Quantitative Effectiveness and Risk Information to Consumers in Direct-to-Consumer (DTC) Broadcast and Print Advertisements for Prescription Drugs

# Quantitative Information in DTC Print and Broadcast Ads Study Purpose

- Preliminary purpose: test different ways of presenting quantitative information about product risks and benefits in DTC television ads

# Quantitative Information in DTC Print and Broadcast Ads Study Status

- Planning stages
- 60-day notice for public comment available by end of 2009

# Brief Summary

How to Improve the Presentation of Brief Summary Information in DTC Print Advertisements

# Brief Summary Studies Overview

- Study I
  - Investigate the current brief summary format
- Study II
  - Test different ways of presenting side effect information
- Study III
  - Test different formats

# Brief Summary Study 1 Purpose

- How do people use the brief summary *in its current form*?
- Does risk information on promotion page affect use of brief summary?

# Brief Summary Study 1

Specific Questions:

- Does risk info or medical condition affect:
  - (1) time spent reading the ad
  - (2) comprehension
  - (3) selecting topics
  - (4) intent to ask doctor for info
- What brief summary topics are most useful

# Brief Summary Study 1 Design

| | Medical Condition | | |
|---|---|---|---|
| | Asthma | High Cholesterol | Excess Weight |
| Low Risk Ad | | | |
| High Risk Ad | | | |


## A New Option for YOU

Are you looking for a new way to help control your asthma? Ask your doctor if prescription Oncazil is right for you!

Oncazil is a new treatment for asthma problems that you take only once a week.

Now you don't have to think about taking a pill every day. Leave that nagging feeling behind for the entire week!

**Oncazil is generally safe and effective.**
Clinical trials have shown that it helps provide safe and effective asthma symptom control. Individual results may vary.

**Important Information:**
Oncazil will not replace fast-acting inhalers for sudden symptoms. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks. In rare cases, Oncazil may cause serious heart valve problems that begin with a noticeable change in heart rhythm. Also, in rare cases, Oncazil may cause a mild and temporary skin sensitivity to heat. If it does not go away in two days, call your doctor. Other side effects include dry mouth, upset stomach and headache.

Please see important information on the next page.

To learn more about a once-a-week treatment, talk to your doctor about Oncazil or go online at www.oncazil.com or call 1-800-ONCAZIL

Oncazil
(strodacazil)
10 mg tablets

KAJ Pharmaceutica

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# ONCAZIL (strodacazil)

This summary contains important information about ONCAZIL ("ON-kah-zeel"). It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking Oncazil. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about Oncazil.

## Oncazil is:

Oncazil is a drug used to treat asthma in adults and children as young as 12 years.

Oncazil will not replace fast-acting inhalers for sudden symptoms. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.

## Who Should Not Use Oncazil

Oncazil should not be used if:
- you have liver damage
- you have experienced a heart attack or stroke
- you have recently had the flu
- you are pregnant

## Medicine Interactions

Tell your doctor if you are taking:
- antibiotics (Oncazil may lose its effectiveness).
- NSAIDs (non-steroidal anti-inflammatories; Advil, Aleve, Motrin) (Can increase the amount of Oncazil in your bloodstream).

## Warnings

**Heart Valve Damage:** Rare but serious heart valve problems have been reported with the use of Oncazil. Generally, these problems begin with a noticeable change in heart rhythm. Notify your doctor immediately if you experience a strange heartbeat pattern, or pain in your chest or down your left arm.

## Precautions

Patients with a history of kidney disease should be monitored carefully and placed on the lowest starting dose of Oncazil (see also **Monitoring Requirements**).

## Side Effects

**Serious but Rare**

Heart valve damage has been noted in rare cases (see also Warnings). Other rare but serious side effects include severe cough and chest pain.

**Common Side Effects**

Other side effects have been reported in those taking Oncazil. These side effects are generally mild or moderate and go away within a few days. These side effects include a temporary skin sensitivity to heat, dry mouth, headache, and upset stomach.

## Special Populations

**Children**

Oncazil has been studied in children as young as twelve years. Children should be given the lowest dosage possible and this dosage should never exceed 100 mg. Patients should be monitored for kidney functioning, as young kidneys may be more sensitive to the effects of Oncazil.

**Elderly**

Oncazil has not been studied in adults over the age of 65.

**Pregnancy**

Oncazil should not be used during pregnancy. Animal studies showed that Oncazil may cause abnormal heart rates in infants before and after birth. It is not clear what consequences this may have for the developing fetus. Therefore, Oncazil is not recommended for use in pregnancy. Tell your doctor if you are pregnant or plan to get pregnant.

## Clinical Trial Information

**What tests were conducted**

Oncazil was studied in three large trials with over 10,000 men and women. Oncazil was compared to placebo (pill with no medicine in it) to see if people controlled their symptoms more than without the drug.

**How long clinical trials lasted**

In two studies, patients took Oncazil for 12 weeks. In the third study, patients were followed for 18 months.

## How Long It Takes to Work

Once you take your first pill, Oncazil will begin working immediately. As long as you remember to take a pill at the same time every week, you will not experience any changes in its effectiveness.

## Different Dosage Forms

Oncazil is available in a once-a-week and a once-a-day formulation. Talk to your doctor about the best dosing form for you.

## Dosing

Your prescription for Oncazil will include up to twelve pills. Choose a time that you can remember each week. At that time, take one tablet with a full glass of water. Take one pill at the same time once a week.

**What to do if a Dose is Missed**

If you forget to take a pill during the first two days, take it as soon as you remember, record the date, and tell your doctor at your next visit. If you remember after the first two days, do not take it until your normally scheduled time and tell your doctor at your next visit.

**Monitoring requirements**

Your doctor will give you a simple kidney monitoring test every 4 months while you are taking Oncazil to check for kidney function changes.

**Ingredients**

Strodacazil, lactose monohydrate, stearic acid, titanium dioxide, red ferric oxide, yellow ferric oxide, carnauba wax.

## What to do in the Case of an Overdose

If you take more than the prescribed amount of Oncazil AND experience sharp pains in your chest, call 911 or go to the nearest emergency room.

## Abuse Potential

Oncazil has not been shown to be habit-forming or cause withdrawal symptoms.

## How Oncazil Works

It is believed that Oncazil changes the function of one of the neurons in the brain that controls respiratory functions.

## Lifestyle Factors to Think About When Taking Oncazil

Oncazil will not take the place of fast-acting inhalers for sudden symptoms. In order to benefit the most from taking Oncazil, talk to your doctor about identifying specific asthma triggers that affect you and how to avoid them.

## Other Food and Medicines You May Be Taking

**Caffeine.** Oncazil does not interact with caffeine.

**Alcohol.** Use caution when drinking alcohol and taking Oncazil. Oncazil may speed up the effects of alcohol.

**Herbal supplements.** Oncazil is not known to interact with any herbal substances, but tell your doctor if you take any.

**Over-the-Counter Drugs.** NSAIDS (Advil, Aleve, Motrin) may cause more of Oncazil to build up in your bloodstream, causing an upset stomach.

## Other Things to Tell the Doctor

- If you develop a temporary skin sensitivity to heat.
- If you are having trouble remembering to take a pill weekly.
- If you experience any lightheadedness and/or weakness.

## Storage

Store Oncazil at room temperature (65-80 degrees F).

## General Information about Prescription Drugs

- Only take for what it is prescribed
- Only take as the doctor instructed
- Do not share this prescription with others

## Reporting Side Effects

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## How to Get More Information

- Talk to your doctor or pharmacist
- Visit www.oncazil.com
- Call 1-800-ONCAZIL

**Rx only**

10 mg tablets

Oncazil
(strodacazil)

KAJ Pharmaceutica
St. Louis, MO

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# Study Protocol

- Mall intercept
- In-depth interview
- Ads were presented on computer (last ad in series of 3 ads)
- Questionnaire following ad

# Measures

- Demographics: gender, age, education, ethnicity, race
- Health Literacy: Rapid Estimate of Adult Literacy in Medicine (scored 0-66; formed quartiles)
- Perceived Risk: How safe/risky? Dangerous/harmless?

  1 (very safe/harmless) to 5 (very risky/dangerous)
- Time: Viewing time on promotion page and brief summary (in milliseconds)

# Measures

- Comprehension: 12 item Correct-Incorrect scale (e.g., “Oncazil has not been shown to be habit forming”)

- Topics selected: Brief summary topics were listed; asked to choose all topics that were useful

  Which topics were selected most often
  Number of topics selected

- Intent to ask doctor: “How likely are you to ask your Doctor about Oncazil?”
  1 (definitely ask) to 5 (definitely not ask)

# Sample Characteristics

Demographics

52% female
55% white
85% non-Hispanic
32% high school graduate or less
Mean Age: 36 years (range 18-81)

Sufferers and Caregivers

79% sufferers (N = 629)
21% caregivers (N = 171)

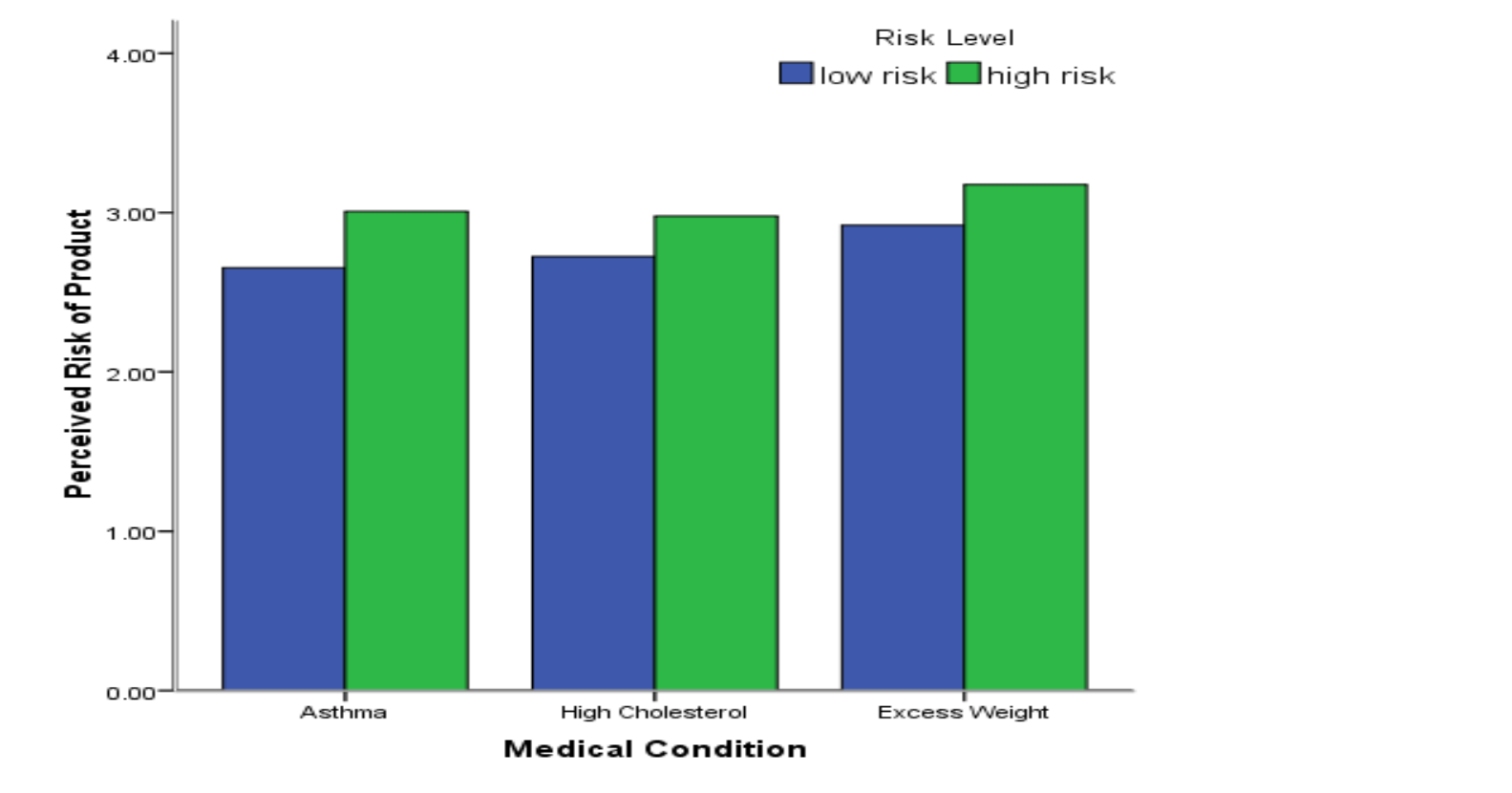
N = 800

# Preliminary Examination of Results

- Manipulation check: Did the manipulation of risk affect risk perceptions?
- Did risk info or medical condition affect:
  - (1) time spent reading the ad
  - (2) comprehension
  - (3) selecting topics
  - (4) intent to ask doctor about product
- What brief summary topics were rated most useful?

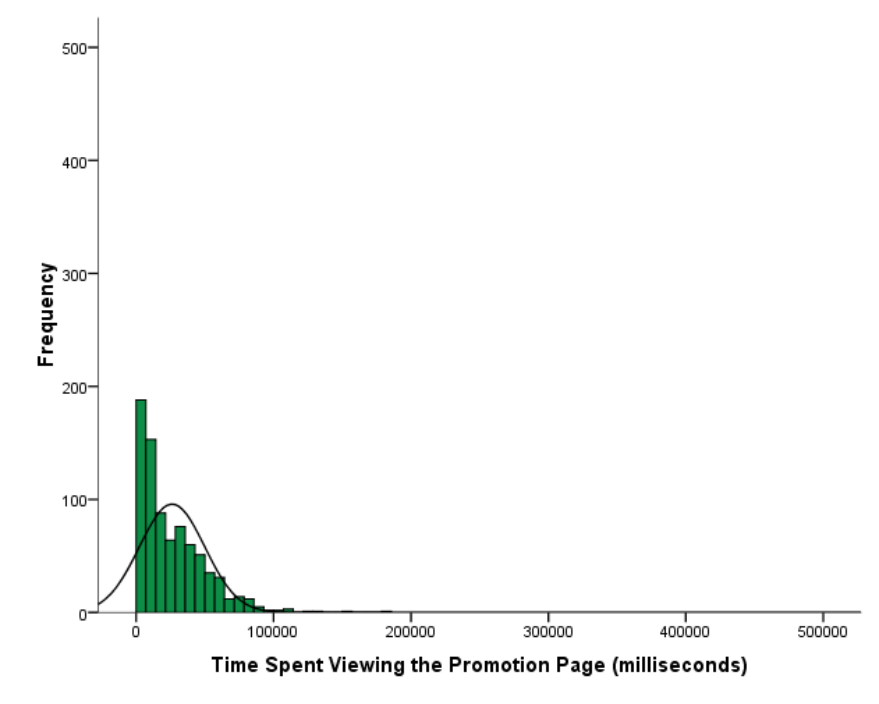
# Manipulation Check

- Participants in all three medical conditions rated the product in the high risk ad as more risky than the product in the low risk ad.



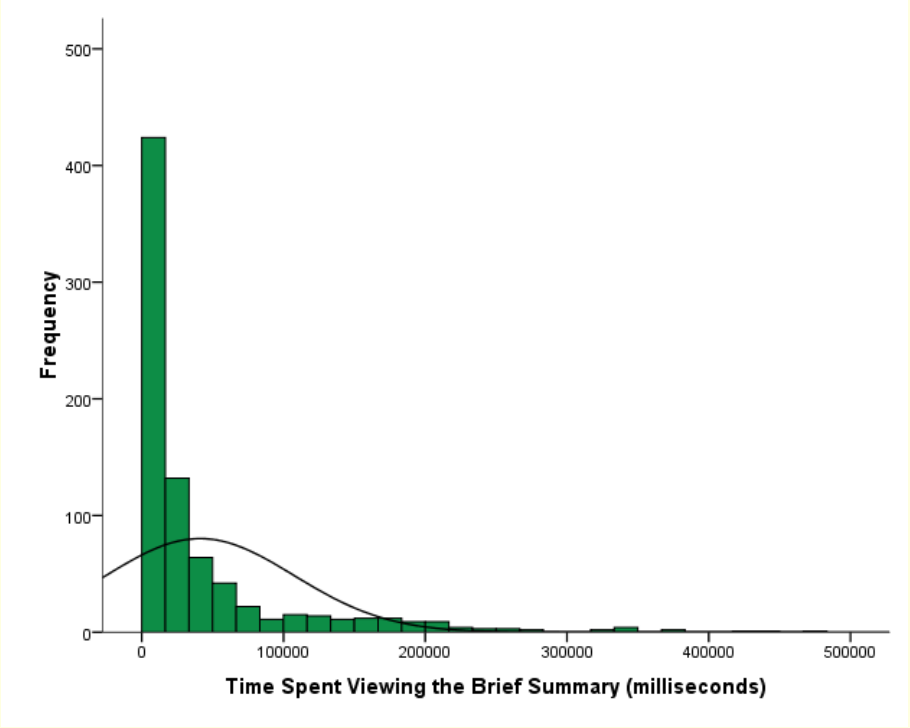
# How much time did participants spend reading the promotion page and the brief summary?

Promotion Page




Average time spent reading the promotion page = 26.12 seconds (Range = 0.52 to 183.38 seconds); median = 18.47 seconds.

Brief Summary




Average time spent reading the brief summary = 41.08 seconds (Range = 0.34 to 478.60 seconds); median = 13.87 seconds.

# Did risk information or medical condition affect time participants spent reading the promotion page and the brief summary?

- No.
  - Adding risk info did not increase or decrease time spent reading the ad ($p > .05$).
  - Results were consistent across medical condition ($p > .05$).

# What did affect time participants spent reading the promotion page and the brief summary?

- **Reading speed**: Slower readers spent more time on the promotion page and brief summary ($p < .05$).
- **Age**: Older participants spent more time on the promotion page and brief summary ($p < .05$).
- **Health Literacy**: Participants in the lowest literacy group spent less time reading the promotion page and the brief summary than participants in other literacy groups ($p < .05$).

# Time Spent on Promotion Page and Brief Summary by Health Literacy Level

| | Health Literacy Level by Quartile | N | Mean Time in seconds (SD) |
|---|---|---|---|
| Promotion Page | 0-24% | 201 | 24.12 (28.07) |
| | 25-49% | 177 | 26.31 (24.16) |
| | 50-74% | 186 | 25.44 (19.75) |
| | 75-100% | 212 | 29.38 (21.60) |
| Brief Summary | 0-24% | 201 | 33.66 (58.68) |
| | 25-49% | 177 | 44.34 (74.86) |
| | 50-74% | 186 | 40.18 (62.68) |
| | 75-100% | 212 | 48.28 (69.39) |

# Did risk information or medical condition affect comprehension?

- Adding risk information did not affect comprehension ($p > .05$).
- **Medical Condition**: Participants in the asthma condition had higher comprehension scores than participants in the weight condition ($p < .05$). There were no other significant effects.

# What else affected comprehension?

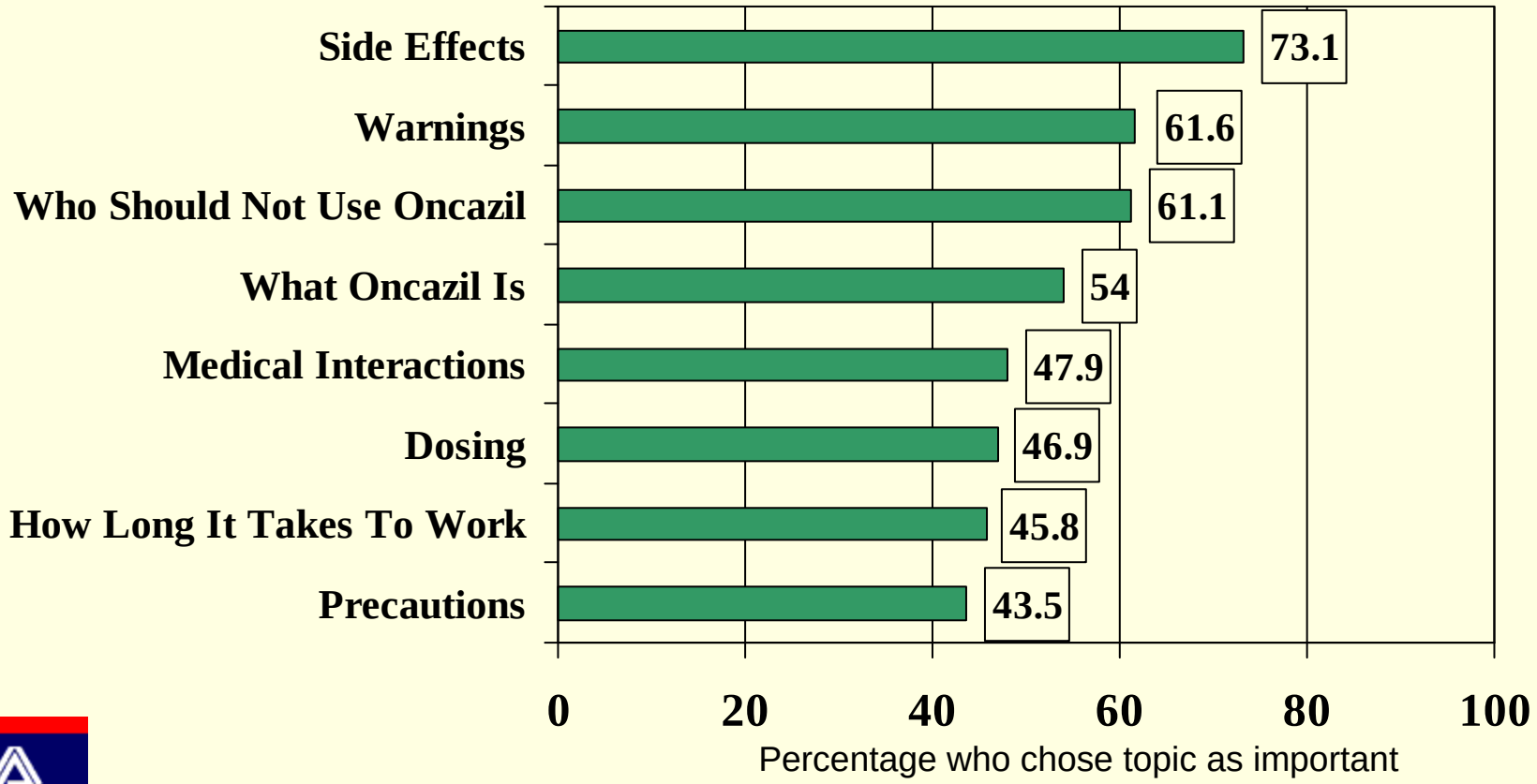
- **Age**: Older participants had greater comprehension ($p < .05$).

# What else affected comprehension?

- **Time spent reading the brief summary**: The more time participants spent on the brief summary, the greater their comprehension ($p < .05$).

# What brief summary topics were selected as useful?

- Mean number of topics selected = 8.37 (SD=6.17), range = 0 to 24.




N = 800, multiple responses permitted

# Did risk information or medical condition affect the number of topics selected as important?

- No.
  - Adding risk info did not affect the number of topics selected ($p > .05$).
  - Results were consistent across medical condition ($p > .05$).

# What did affect the number of topics selected as important?

- **Age**: Older participants selected more topics as important ($p < .05$).
- **Health Literacy**: Participants in the lowest quartile selected fewer topics than participants in every other quartile ($p < .05$).

# Mean Number of Topics Selected as Important While Reading the Brief Summary, by Health Literacy Level

| Health Literacy Level by Quartile | N | Mean (SD) |
|---|---|---|
| 0-24% | 201 | 6.58 (5.84) |
| 25-49% | 177 | 8.54 (6.60) |
| 50-74% | 186 | 9.23 (6.19) |
| 75-100% | 212 | 9.46 (5.72) |

# What did affect the number of topics selected as important?

- **Time spent reading the brief summary**: The more time participants spent on the brief summary, the more topics they selected ($p < .05$).

# Did risk information or medical condition affect intent to ask doctor about the product?

- Adding risk info did not affect intent to ask doctor ($p > .05$).
- **Medical condition**: Participants in the asthma condition reported greater intentions to ask the doctor than those in the cholesterol or weight conditions. Participants in the cholesterol condition reported greater intentions than those in the weight condition ($ps < .05$).

Note: These preliminary analyses were conducted with sufferers only; N = 629.

# What else affected intent to ask doctor?

- **Age**: Older participants had greater intentions to ask the doctor about the product ($p < .05$).
- **Race**: Non-white participants had greater intentions to ask the doctor about the product than did white participants ($p < .05$).

Note: These preliminary analyses were conducted with sufferers only; N = 629.

# What else affected intent to ask doctor?

- **Time spent reading the brief summary**: The more time participants spent on the brief summary, the greater their intentions to ask the doctor about product ($p < .05$).

Note: These preliminary analyses were conducted with sufferers only; N = 629.

# Preliminary Conclusions

Adding a serious risk did not impede searching for further information (did not decrease time, comprehension, number

of topics selected, or intent to ask doctor)

In general, results were consistent across medical conditions

Time spent on the ad predicted comprehension, number of topics selected and intent to ask doctor

Health literacy and age also appear to be important predictors

# Online FDA Resources

- General FDA information:
  - http://www.fda.gov
- DDMAC home page:
  - http://www.fda.gov/cder/ddmac
- Interested in a DDMAC job?:
  - Email DDMACJOBS@fda.hhs.gov
- Untitled and Warning Letters:
  - http://www.fda.gov/cder/warn/index.htm

Contact info: kathryn.aikin@fda.hhs.gov